IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* AARON SHILOH, M.D., FSIR, Plaintiff, v. PHILADELPHIA VASCULAR INSTITUTE, LLC, and JAMES McGUCKIN, M.D., Defendants, and PENNSYLVANIA VASCULAR INSTITUTE, PC, LEHIGH VALLEY VASCULAR INSTITUTE LLC, MAIN LINE VASCULAR INSTITUTE LLC, PA VASCULAR INSTITUTE LLC, and PERIPHERAL VASCULAR INSTITUTE OF PHILADELPHIA LLC, Additional Defendants.	:	Civil Action No. 18-cv-5458

COMPLAINT IN INTERVENTION

The United States brings this action under the False Claims Act, 31 U.S.C. § 3729 *et seq*. (the "FCA") against Dr. James McGuckin ("McGuckin") and his practices and management companies (collectively, "Defendants") for knowingly submitting or causing the submission of false claims to federal health care programs for medically unnecessary invasive vascular procedures and knowingly making false statements to the government related to those procedures. Defendants were also unjustly enriched by this conduct in violation of state law.

Between at least January 1, 2016 and December 31, 2019 (the "relevant period"), McGuckin engaged in a pattern and practice of performing and billing federal health care programs for an excessive number of invasive procedures for the purported treatment of Peripheral Artery Disease ("PAD"), including angioplasty, atherectomy, and stent implantation, and the indiscriminate use of Intravenous Ultrasound ("IVUS"). Instead of performing these higher risk procedures in accordance with widely accepted standards of care and applicable federal healthcare program rules—that is, *only* on patients with lifestyle-limiting leg pain when walking, *only* after exhausting non-invasive alternative therapies, and *only* performing those procedures that the evidence showed were warranted—McGuckin regularly subjected patients to invasive peripheral artery procedures without regard to patient need and without properly evaluating and documenting the medical necessity of each procedure.

In one case, he performed multiple procedures for leg pain when walking on a patient who, due to paralysis on one side of her body, did not walk at all. In another case, he performed multiple unnecessary below-the-knee procedures in the small portion of what remained of a patient's already amputated leg, without any medical justification. In other cases, he billed Medicare for procedures for which there is no record that he performed at all. And by his own admission, McGuckin has performed invasive procedures on patients with only "moderate" leg pain—confirming that these procedures are not only medically unnecessary, but *contraindicated* by the applicable standards of care.

Defendants knew, deliberately ignored, or recklessly disregarded the fact that many of the endovascular procedures for which they submitted claims to federal healthcare programs were not justified by patients' medical histories and records, or the severity of patients' symptoms, or appropriately documented as either, as federal payment rules require. Nevertheless, with each claim, Defendants falsely certified that the procedures were medically necessary.

Defendants' fraudulent conduct made McGuckin one of the highest paid providers for PAD procedures in the country. Between 2016-2019, McGuckin was paid over $6.5 million for over 500 claims for medically unnecessary PAD procedures he personally performed.

By presenting false claims to federal healthcare programs for excessive and medically unnecessary vascular procedures, Defendants caused the United States to pay millions of dollars in false claims, for which the government now seeks damages and penalties under the FCA. A nonexhaustive list of examples of such false claims is attached as Exhibit "A" and incorporated herein by reference.

I. THE PARTIES

1. The United States brings this action on behalf of the U.S. Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program, 42 U.S.C. §§ 1395 *et seq*. ("Medicare"); and the U.S. Office of Personnel Management ("OPM"), which administers the Federal Employee Health Benefits Program ("FEHBP").

2. Relator, Dr. Aaron Shiloh, is a citizen and resident of Pennsylvania. Dr. Shiloh filed this action against McGuckin and defendant Philadelphia Vascular Institute LLC in December 2018 under the *qui tam* provisions of the FCA.

3. On February 28, 2023, the United States intervened in the action.

4. McGuckin is an interventional radiologist licensed to practice medicine in Pennsylvania and residing in Radnor, Pennsylvania. McGuckin owns and operates, either directly or indirectly, multiple vascular practices across the country, including, during the relevant time period, the defendant entities named herein.

5. Defendant Philadelphia Vascular Institute LLC ("PVI") is a limited liability corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 585 County Line Road, Radnor, Pennsylvania, 19087. McGuckin owns 100% of PVI.

6. Additional defendant Pennsylvania Vascular Institute, PC ("PA PC") is a professional corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 31 DeKalb Pike, Blue Bell, Pennsylvania, 19423. McGuckin owns 100% of PA PC, which in turn owns 100% of the following three additional defendants.

7. Additional defendant Lehigh Valley Vascular Institute LLC ("LVVI") is a limited liability corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 3450 Highpoint Blvd., Bethlehem, Pennsylvania 18017.

8. Additional defendant PA Vascular Institute LLC ("PAVI") is a limited liability corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 505 Independence Road, Suite E, East Stroudsburg, Pennsylvania 18301.

9. Additional defendant Peripheral Vascular Institute of Philadelphia LLC ("PVIP") is a limited liability corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 4220 Market Street, 2nd Floor, Philadelphia, Pennsylvania 19104.

10. Additional defendant Main Line Vascular Institute LLC ("MLVI") is a limited liability corporation that exists and operates pursuant to the laws of the Commonwealth of Pennsylvania with a principal place of business at 700 S. Henderson Road, Suite 304A, King of Prussia, Pennsylvania 19406. PA PC owns 67% of MLVI.

11. Throughout the relevant period, McGuckin and defendants MLVI, LVVI, PAVI, and PVIP (the "Defendant Practices") were in the business of providing endovascular services to Medicare and FEHBP beneficiaries. McGuckin and Defendants PVI and PA PC (the "Management Defendants") maintained ownership interests in and managed the Defendant Practices, and, upon information and belief, were the recipients of monies the government paid for the false claims described herein.

12. Throughout the relevant period, McGuckin owned and performed PAD procedures at each of the Defendant Practices. Defendants submitted claims for

payment for these procedures to Medicare and the FEHBP, or caused the submission of the same.

13. In the spring of 2022, McGuckin sold the Defendant Practices other than PAVI (which had ceased operating) to Metro Physicians Specialty Group, P.C. ("Metro"). Metro is owned by Wayne Arnold, M.D.—a physician who throughout the relevant period regularly referred patients to McGuckin. According to Dr. Arnold, McGuckin approached him in January 2022 with a proposal to sell the relevant Defendant Practices, "which he was looking to transfer out of his own name." *See* Petition to Strike or, in the Alternative, Open Confessed Judgment, *McGuckin v. Metro Physicians Specialty Group, P.C.*, Phila. Ct. of Common Pleas No. 202202320 (the "McGuckin Confessed Judgment Action"), Nov. 28, 2022, at ¶ 2. According to publicly available records, the sale took place effective April 2022.

14. In January 2023, as part of the settlement of the McGuckin Confessed Judgment Action, Dr. Arnold and Metro transferred the relevant Defendant Practices to Vascular Care Specialists, LLC. Upon information and belief, Vascular Care Specialists, LLC is owned, at least in part, by McGuckin.

15. McGuckin further appears to have terminated PAVI as a going concern in August 2022, although the East Stroudsburg location remains active as an additional site of service of LVVI.

16. At the time of these transactions, McGuckin knew that he and the defendant entities were under investigation by the United States for violations of the False Claims Act. Despite this knowledge, McGuckin initiated these

transactions without notice to the United States and in an apparent attempt to dissipate his assets. Upon information and belief, McGuckin continues to practice at, and serve as the Medical Director of, and authorized official[1] for, the Defendant Practices.

17. McGuckin admits that he disregards the corporate structure of his entities and treats them all (and their assets) as interchangeable, such that all are jointly and severally liable for McGuckin's false claims to government payors. In sworn testimony in a bankruptcy proceeding he initiated on behalf of a different set of vascular practices he owns, McGuckin testified that he essentially considered PVI, PAVI, PVIP, and himself "to be the same entity since all of the money came from him." *In re Vascular Access Ctrs., L.P.*, 611 B.R. 742, 759 (Bankr. E.D. Pa. 2020):

> Bankruptcy Judge Ashely M. Chan: In your view, PVI, Peripheral Vascular, PA Vascular, James and Allison McGuckin are all basically the same—it's from the same pot, it's your money, right?
>
> McGuckin: Yes.
>
> Judge Chan: So when they said, well how much is PVI owed, you said they they're owed 1.2, because you view all of those entities as one entity?
>
> McGuckin: Yes.

[1] An authorized official is an appointed person with the legal authority to make changes and/or updates to the provider's status (*e.g.*, change of address, etc.) and to commit the provider to fully abide by the laws and regulations relating to the National Provider Identifier.

Tr. of Hearing held on Feb. 6, 2020 in *In re Vascular Access Ctrs.*, Bankr. Case No. 19-17117 (Bankr. E.D. Pa.) at 180:18-181:1 (cleaned up).[2]

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345. This civil action arises under the laws of the United States and is brought by the United States as a plaintiff pursuant to the FCA.

19. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), as McGuckin and five of the six defendant entities reside and transact business in this district, and because acts proscribed by the FCA occurred in (or were directed by McGuckin or the Management Defendants from) this district.

20. Venue is proper pursuant to 28 U.S.C. §§ 1391(b)–(c) and 31 U.S.C. § 3732(a) because: (1) McGuckin resides and transacts business in this district; (2) all Defendants reside in the Commonwealth of Pennsylvania; and (3) McGuckin performed, and/or Defendants submitted or caused to be submitted false claims for, medically unnecessary procedures in violation of the FCA in this district.

[2] Judge Chan found that McGuckin had orchestrated the bankruptcy filing "in bad faith," and made false representations to the Court on behalf of PVI during the course of those proceedings, subjecting him to sanctions by the Court. *Id*. at 760, appeal to district court pending.

III. STATUTORY AND REGULATORY FRAMEWORK

A. The False Claims Act

21. The FCA provides that any person or entity that knowingly presents, or causes to be presented, a false claim for payment or approval, or a false statement that is material to a claim for payment or approval, is liable to the United States for damages and penalties. *See* 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B).

22. The FCA defines "knowingly" as meaning that a defendant: "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required to show that a person acted knowingly under the FCA. *Id*.

23. The FCA provides that any person who violates the FCA is liable to the United States for three times the amount of damages which the United States sustains because of the act of that person, plus a civil penalty of not less than $5,000 and not more than $10,000 for each claim, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5 (noting currently applicable penalties of not less than $13,508 and not more than $27,018 for each false claim).

B. The Medicare Program

24. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., known as the Medicare program. Entitlement to Medicare is

based on age, disability, or end-stage renal disease. 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, an agency within HHS.

25. The Medicare program consists of four parts: A, B, C, and D. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

26. Medicare Part B covers outpatient care, including physician services and ancillary services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k.

27. Eligible persons may enroll in Part B of the Medicare program, which covers benefits including outpatient surgical procedures that have been performed by a physician. 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(s)(5); 42 C.F.R. § 410.36(a)(1).

28. At all times relevant to this complaint, CMS contracted with private contractors called Medicare Administrative Contractors ("MACs") to perform certain administrative functions on CMS's behalf, including reviewing and paying claims submitted by Medicare Part B healthcare providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104, 421.200.

29. Medicare pays only for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). To this end, Medicare providers must assure that their services are rendered "economically and only when, and to the extent, medically necessary," and that their services are "of a

quality which meets professionally recognized standards of health care." 42 U.S.C. §§ 1320c-5(a)(l) and 5(a)(2).

30. The Medicare Program only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

31. Payment will be made if medical necessity can be substantiated. Section 1862(a)(1) of the Social Security Act; CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Ch. 16, sec. 20.

32. CMS may issue National Coverage Determinations ("NCDs"). 42 U.S.C. § 1395ff(c)(ii)(I), (f)(1), 42 C.F.R. § 405.1060. Separately, the CMS Administrator may also issue rulings that are binding on CMS components, including Medicare Administrative Contractors ("MACs"), which administer payment for the Medicare Program. 42 C.F.R. § 405.1063(b).

33. In the absence of an NCD, MACs may make a Local Coverage Determination ("LCD") as to whether or not a particular item or service is covered as reasonable and necessary within their jurisdiction. 42 U.S.C. §§ 1395ff(c)(ii)(II), (f)(2); 42 C.F.R. § 405.1062. At all times relevant to this action, Novitas Solutions, Inc. has been the Part B MAC for Pennsylvania.

34. In the absence of an LCD, MACs still decide what is reasonable and necessary for payment of claims. Pursuant to CMS Ruling 95.1, MACs look to "locally acceptable standards of practice." *See also* CMS Manual System, Pub, 100-

04, Medicare Claims Processing Manual, Ch. 30, sec. 30.2.3. In determining what "acceptable standards of practice" exist within the local medical community, MACs rely on, among other things, published medical literature (*e.g.*, peer-reviewed journal articles) and a consensus of expert medical opinion. *Id.* Providers are always responsible for knowing locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. *Id.* Also, providers are deemed to know that MACs will deny coverage if services do not meet locally acceptable standards of practice. *Id.*

1. Enrollment in the Medicare Program

35. As a condition to becoming a Medicare provider, Part B providers make certifications to the federal government in provider enrollment agreements on CMS Form 855b (Medicare Enrollment Application for clinics/group practices and certain other suppliers) and/or CMS Form 855i (Medicare Enrollment Application for physicians and certain non-physician practitioners), including:

> I agree to abide by the Medicare laws, regulations and program instructions . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> ***
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

36. Relying on the veracity of these certifications, CMS makes Medicare payments retrospectively (*i.e.*, after the services are rendered) to Part B providers. For this reason, Medicare payments are often referred to as reimbursements.

37. McGuckin has been registered as a Medicare provider in Pennsylvania since at least 2010 and has executed at least one provider enrollment agreement.

38. Defendant PVI has been registered as a Medicare provider in Pennsylvania since at least 2012 and has executed at least one provider enrollment agreement.

39. Defendant Practice PAVI has been registered as a Medicare provider in Pennsylvania since at least 2012 and has executed at least one provider enrollment agreement.

40. Defendant Practice LVVI has been registered as a Medicare provider in Pennsylvania since at least March 2017 and has executed at least one provider enrollment agreement.

41. Defendant Practice MLVI has been registered as a Medicare provider in Pennsylvania since at least 2015 and has executed at least one provider enrollment agreement.

42. Defendant Practice PVIP has been registered as a Medicare provider in Pennsylvania since at least 2010 and has executed at least one provider enrollment agreement.

2. Submitting Medicare Claims for Reimbursement

43. To obtain reimbursement from the Medicare Program, providers submit a claim form, CMS Form 1500 and/or its electronic equivalent, known as the 837P form.

44. In submitting the form to CMS, providers certify, among other things, that their services were medically necessary.

45. Among the information the provider includes on a CMS 1500 or 837P Form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Ch. 23, § 20.7 *et seq*. CPT codes are widely used in the United States as the way medical providers seek reimbursement for professional services from healthcare payors, including Medicare, other federal healthcare programs, and many private insurers.

46. HCPCS Level II codes are widely used in the United States as the way medical providers seek reimbursement for medical products, supplies, and equipment from healthcare payors, including Medicare, other federal healthcare programs, and many private insurers.

47. The American Medical Association ("AMA") defines the CPT and HCPCS codes in manuals published annually.

48. At all relevant times, the AMA coding manual has stated these instructions for selecting appropriate codes: "Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided."

49. Providing accurate CPT and HCPCS codes on claims submission forms is material to and a condition of payment for the Medicare Program. *See, e.g.*, Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

50. The Medicare Program routinely denies payment to providers who bill for codes when the criteria for those codes are not actually met, including when the services are not performed.

51. Any provider seeking Medicare reimbursement through Part B must certify on a CMS-1500 or 837P that "the services shown on this form were medically indicated and necessary for the health of the patient[.]"

52. Both the CMS 1500 and the 837B include an express certification from the provider that the claim is "accurate, complete, and truthful."

53. The 837B also includes an acknowledgment "that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law."

54. CMS Form 1500 includes an express certification from the provider that "the claim, whether submitted by me or on my behalf by a designated billing company, complies with all applicable Medicare and/or Medicaid law, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute."

55. CMS Form 1500 also includes a certification that the party submitting the form has: (1) "familiarized [itself] with all applicable laws, regulations, and program instructions;" and (2) "provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision."

56. Because it is not feasible for Medicare personnel to review every patient's medical records for the millions of claims for payments they receive from providers, the program relies on providers to comply with Medicare requirements and trusts providers to submit truthful and accurate certifications and claims.

57. Generally, once a provider submits CMS Form 1500 or the 837B Form to Medicare, the claim is paid directly to the provider without any review of supporting documentation, including medical records.

3. Copayments

58. As a general matter, Medicare Part B covers 80 percent of the reasonable cost of medical services, with the remaining 20 percent being owed by the beneficiary as a copayment obligation. *See*, *e.g.*, 42 U.S.C. § 1395m(a); 42 C.F.R. § 414.210(a); *see also* OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19,

1994) ("Copayment . . . is the portion of the cost of an item or service which the Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance is generally 20 percent of the reasonable charge for the item or service.").

59. Thus, except in rare circumstances, providers are required to collect the full 20 percent copayment from Medicare beneficiaries or their secondary insurers. Moreover, as is made clear in the Medicare Claims Processing Manual, a "reasonable collection effort" must be made to collect the copayment, which requires, at minimum, "a genuine, rather than token, collection effort." Medicare Claims Processing Manual, Chapter 23, §80.8.1.

C. The Anti-Kickback Statute

60. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these harms, Congress enacted a prohibition against payment of kickbacks in any form. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

61. The AKS prohibits any person or entity from knowingly and willfully soliciting or receiving remuneration to induce or reward any person for referring,

recommending, or arranging for federally funded medical services, including services provided under the Medicare program. *See* 42 U.S.C. § 1320a-7b(b).

62. The scienter element of the AKS is established by showing that "one purpose" of the remuneration at issue was to induce purchases or referrals, even if the remuneration also had other purposes that were legitimate. *See*, *e.g.*, *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *see also United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998). The AKS provides that: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

63. A violation of the AKS is established when "at least one" claim submitted to a federal healthcare program links to the alleged kickback scheme. *See*, *e.g.*, *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018). The AKS does not require the government to demonstrate that federal beneficiaries would not have used the services at issue "but for" the alleged kickback, nor does it require a showing that a kickback directly influenced a patient's decision to use those services. *Id*.

64. As a matter of law, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g); *see also United States ex rel. Strunck v. Mallincrodt*

Ard LLC, Civ. Nos. 12-175, 13-1776, 2020 U.S. Dist. LEXIS 10191, at *25 (E.D. Pa. Jan. 21, 2020) (Schiller, J.) ("AKS violations are *per se* material under the FCA.").

65. In the Patient Protection and Affordable Care Act ("ACA"), Congress intended to codify the pre-existing legal consensus "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854 (daily ed. Dec. 21, 2010); *see also United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (holding that under the pre-ACA AKS, all claims resulting from illicit kickbacks constituted false claims under the FCA); *see also United States ex rel. Capshaw v. White*, No. 3:12-cv-4457, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018) (Godbey, J.).

66. A claim for reimbursement from a Federal health care program for items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a)(1)(A)-(B). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

67. The waiver, forgiveness, or failure to collect Medicare copayments constitutes the payment of "remuneration" under the AKS.

68. Consequently, it is a violation of the AKS, and thus the FCA, for a party to knowingly and willfully routinely waive or fail to collect Medicare copayments to induce a Medicare beneficiary to purchase any item that will be paid in whole or in part by Medicare.

69. The Officer of the Inspector General for HHS ("HHS-OIG") has issued fraud alerts with respect to the waiver of copayment obligations for beneficiaries of federal health care programs.

70. The first fraud alert on this topic was issued in 1994. In that document, HHS-OIG declared that the "[r]outine waiver of deductibles and copayments . . . is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

71. This is because a "provider, practitioner, or supplier who routinely waives Medicare copayments or deductibles is misstating [to CMS the] actual charge" of the item. *Id*. By way of example, "if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80." *Id*. "As a result of the supplier's misrepresentation, the Medicare program is paying . . . more than it should for this item." *Id*.

72. Even if non-routine, the waiver of a copayment is permissible only in narrow circumstances. The waiver must be: (1) unadvertised; and must either (2) "address the special financial needs of a particular patient;" or (3) occur after "a good faith effort to collect" has been exhausted. *Id.* at 65375; *see also* 42 U.S.C. §

1320a-7a(i)(6) (prohibited remuneration does not include "the waiver of coinsurance" if: (i) "the waiver is not offered as part of any advertisement or solicitation;" (ii) "the person does not routinely waive coinsurance;" and (iii) the person determined "in good faith that the individual is in financial need" or failed to collect "after making reasonable collection efforts"); 42 C.F.R. § 1003.101 (same).

73. Relying on OIG's guidance on this issue, CMS's Medicare Claims Processing Manual explains that deductible and coinsurance amounts are included in determining the reasonable charge for a service or item. In this regard, a billed amount that is not reasonably related to an expectation of payment is not considered the "actual" charge for the purpose of processing a claim or for the purpose of determining customary charges. Medicare Claims Processing Manual, Chapter 23, § 80.8.1. 69. In the 1994 fraud alert, HHS-OIG provided a non-exhaustive list of indicators of improper copayment waivers, including:

- Advertisements which state: "Medicare Accepted as Payment in Full," "Insurance Accepted as Payment in Full," or "No Out-Of-Pocket Expense." Advertisements which promise that "discounts" will be given to Medicare beneficiaries.
- Routine use of "Financial Hardship" forms which state that the beneficiary is unable to pay the coinsurance/deductible (*i.e.*, there is no good faith attempt to determine the beneficiary's actual financial condition).
- Collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance ("Medigap") coverage (*i.e.*, the items or services are "free" to the beneficiary).
- Charges to Medicare beneficiaries which are higher than those made to other persons for similar services and items (the higher charges offset the waiver of coinsurance).

- Failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (*e.g.*, a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals).

- "Insurance programs" which cover copayments or deductibles only for items or services provided by the entity offering the insurance.

- The "insurance premium" paid by the beneficiary is insignificant and can be as low as $1 a month or even $1 a year. These premiums are not based upon actuarial risks, but instead are a sham used to disguise the routine waiver of copayments and deductibles.

OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

74. In a 2014 fraud alert, HHS-OIG reiterated its "longstanding" position that "[p]roviders and suppliers that routinely waive cost-sharing amounts . . . may be held liable under the anti-kickback statute." 79 Fed. Reg. 59717, 59720 (Oct. 3, 2014). This is because "[s]uch waivers may constitute prohibited remuneration to induce referrals under the anti-kickback statute. . . ." *Id.*

75. HHS-OIG has recognized a limited "exception to the prohibition against waiving copayments." OIG Special Fraud Alert, 59 Fed. Reg. 65372-01 (Dec. 19, 1994). Under this limited exception, "suppliers may forgive the copayment in consideration of a particular patient's financial hardship." *Id.*

76. However, HHS-OIG has emphasized that: (1) "this hardship exception . . . must not be used routinely; it should be used occasionally to address the specific financial need of a particular patient;" and (2) "a good faith effort to collect . . . copayments must be made." *Id.*

D. The Federal Employee Health Benefits Program

77. The FEHBP is a federally funded insurance program established by Congress in 1959 pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. § 8901 *et seq*. FEHBP is for federal employees, retirees, and their spouses and unmarried children under the age of 26. 5 C.F.R. § 890.302.

78. OPM administers FEHBP and contracts with various health insurance carriers ("Carriers") to provide services to FEHBP members. 5 U.S.C. §§ 8902, 8909(a). Benefits provided to FEHBP members include outpatient surgical procedures that have been performed by a physician.

79. Monies for the FEHBP are maintained by the United States Treasury in the Employees Health Benefits Fund ("the Fund"), which OPM administers. 5 U.S.C. § 8909(a). The Fund—which the United States Treasury holds and invests—is the source of all relevant payments to the Carriers for services rendered to FEHBP members. 5 U.S.C. § 8909.

80. Federal agencies and their employees contribute to the Fund through health insurance premiums, referred to as contributions. 5 U.S.C. § 8906. Federal employees' portions of the contribution are withheld from each paycheck, then forwarded to the Fund by the employing agency, along with the agency's share of the premium. 5 U.S.C. § 8906(d), (e). The Treasury holds and invests the Treasury Fund balances. 5 U.S.C. § 8909. Proceeds from the Fund are used to pay Carriers for covered claims paid on behalf of FEHBP members.

81. Carriers do not have any right to monies from the Treasury for reimbursement of benefits unless and until they incur legitimate costs for actual covered services rendered to the members and submit claims to the Government for the payment for those services. FEHBP benefits are payable only for services necessary to prevent, diagnose, or treat an illness, disease, injury, or condition.

IV. FACTUAL BACKGROUND

A. Peripheral Artery Disease

82. Peripheral artery disease ("PAD") is the narrowing or blockage of peripheral arteries in and consequent reduction of blood flow to the legs.

83. PAD is usually caused by atherosclerosis—the buildup of cholesterol and fatty deposits called "plaques" on the inner walls of the arteries. Plaques restrict blood flow to the limbs and other parts of the body by clogging arteries or causing abnormal artery function. Vascular specialists and other medical professionals refer to this narrowing or blockage as a "lesion" or "stenosis."

84. PAD includes a spectrum of syndromes ranging from intermittent "claudication" to "chronic limb-threatening ischemia." Claudication is exertional leg pain caused by obstructed arteries. Chronic limb-threatening ischemia (referred to in older literature as "critical limb ischemia") usually involves non-exertional or resting leg pain, non-healing wounds, ulcers, or gangrene. Most patients with PAD have only intermittent claudication, which usually does not require invasive measures for treatment, and is typically unlikely to progress to critical limb ischemia.

B. The Standard of Care for the Treatment of, and Performance of Invasive Procedures for, PAD

85. The standards of care for the treatment of PAD are straightforward and commonly known, and depend almost entirely on a patient's symptoms. An estimated 1 in 14 adults has some degree of PAD. But intermittent claudication only requires intervention in very limited circumstances where it significantly impacts a patient's active lifestyle and where noninvasive measures—such as lifestyle changes, medication, and supervised exercise therapy—have proven unsuccessful in mitigating the patient's symptoms. Peripheral arteries may be significantly or completely blocked and still not require intervention because more than one artery supplies blood to the peripheral tissue.

86. Accordingly,

> Interventions for claudication are done to improve function in the setting of significant ongoing disability in an active person. In this context, it is important to recognize that some patients seek treatment based solely on the fear that [intermittent claudication] will inexorably lead to amputation. Reassurance about the expected natural history of claudication to alleviate their anxiety may be all that is required in such patients and should always predate a discussion of invasive treatment. *Performing prophylactic interventions in patients with [intermittent claudication] that is minimally symptomatic or well tolerated has no benefit, may cause harm, and is never indicated*.

Conte *et al.*, "Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication," 61 Journal of Vascular Surgery S2, 15S (2015) (emphasis added).

87. Additionally, evidence indicates that performing invasive PAD procedures for intermittent claudication actually increases a patient's risk for

eventual amputation. Leading authorities, including the National Preventative Services Task Force, recommend against routine screening for PAD because such screening provides little demonstrated value and leads to unnecessary and excessive treatment.

88. Professional guidelines similarly caution that endovascular procedures should not be performed in patients with intermittent claudication solely to prevent progression of the disease. *See*, *e.g.*, 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease.

89. These clear guidelines notwithstanding, with lucrative reimbursement rates for certain PAD procedures in outpatient settings, practitioners have recognized the overtreatment of intermittent claudication, particularly in vulnerable minority populations, as a significant source of false claims and potential patient harm. *See*, *e.g.*, Sumathi Reddy, "Doctors Sound an Alarm Over Leg-Stent Surgery," Wall Street Journal, Sept. 10, 2019.

90. These clinical indications of the medical necessity of invasive peripheral artery procedures are set forth consistently in national guidelines issued by professional medical associations including the American College of Cardiology Appropriate Use Criteria Task Force ("ACC"), the American Heart Association ("AHA"), the Society for Cardiovascular Angiography and Interventions ("SCAI"), the Society of Interventional Radiology ("SIR"), and Society for Vascular Medicine ("SVM"). As discussed below, Medicare's reimbursement standards and applicable

Local Coverage Determinations reflect this commonly accepted and uncontroversial standard of care.

C. The Standard Workup for Patients Suspected of Having PAD

91. PAD that is significant enough to warrant treatment must be specifically and appropriately evaluated, diagnosed, and managed. Accordingly, a provider must evaluate the severity of a patient's PAD based on the patient's symptoms and functionality through non-invasive testing and non-invasive treatment methods before resorting to invasive procedures.

92. Commonly used non-invasive testing for PAD includes physical examination for, among other things, a diminished pulse; a whooshing sound (or "bruit") heard over arteries using a stethoscope; and poor wound healing in areas where blood flow may be restricted. Another technique compares systolic blood pressure in the ankle to systolic blood pressure in the arm, and evaluates the resulting ratio, referred to as the "ankle-brachial index" ("ABI").

93. Other, more sophisticated non-invasive testing for PAD involves techniques like measuring transcutaneous oxygen pressure ("TCPO2") of the toes; segmental blood pressure recordings; pulse volume recordings ("PVRs"); Doppler flow measurements with ultrasound (or "lower extremity arterial Duplex"); magnetic resonance angiography ("MRA"); and computerized tomography angiography ("CTA"). MRA and CTA involve the injection of contrast material (or "dye") into the blood vessels to enable the cardiovascular specialist to view vascular anatomy without using an invasive, catheter-based approach.

94. However, even if PAD is identified on imaging, intervention is not always necessary or appropriate.

95. Patients with asymptomatic PAD should not undergo an intervention.

96. Patients with intermittent claudication should be treated with medical management first. This non-invasive treatment for PAD includes dietary modifications, exercise programs, risk factor modification (especially smoking cessation where applicable), and medications such as aspirin, statins (cholesterol-lowering drugs), and, in some patients, cilostazol (the generic name of a drug used to treat claudication). If the patient's symptoms are still lifestyle limiting after 3-6 months of conservative management, intervention can be considered. If a patient's symptoms are not lifestyle limiting, intervention is not indicated.

97. If non-invasive tests corroborate the severity of the PAD—and if disabling claudication or critical limb ischemia (including rest pain or tissue loss) has developed—a physician may perform invasive testing to determine if "revascularization" is necessary. Revascularization refers to the use of invasive techniques, either catheter-based or surgical, to restore adequate blood flow to the affected limb and relieve symptoms.

98. Catheter-based angiography, or an "angiogram," is an invasive imaging procedure that involves the insertion of a long, narrow tube called a "catheter" into a blood vessel in the arm or leg. The catheter is guided through the blood vessel to the artery of interest with the aid of an x-ray imaging technique

called fluoroscopy. Dye is injected through the catheter into the vessel to make its internal dimensions visible.

99. When warranted and clinically indicated, and only after noninvasive treatment and medical management have failed, invasive imaging such as an angiogram may be appropriate to determine the location and extent of an artery lesion or blockage.

100. In the lower extremities, lesions creating greater than 50% stenosis are considered moderate and lesions creating greater than 70% stenosis are considered severe. Lesions with less than 50% stenosis do not require intervention. Indications for intervention on moderate lesions depend on the patient's symptoms, but generally do not require intervention. Severe lesions are generally appropriate for intervention, but again depend on the patient's symptoms.

101. Once an evidence-based decision has been made to perform an intervention for PAD, the practitioner must decide both where in the leg the intervention is needed and what intervention (or, in some cases, interventions) to perform.

102. The appropriate anatomic zone for treatment depends on the indication for intervention. In the lower extremities, lesions can be located in arteries in the upper leg (femoral artery and popliteal artery), the lower leg (anterior tibial artery, posterior tibial artery, or peroneal artery, termed tibial arteries), or the foot (dorsalis pedis artery or the plantar arch or related branches, termed pedal arteries). Lesions located in the femoral and popliteal arteries

typically cause intermittent claudication due to reduced blood flow to the calf muscles when walking. Lesions in the tibial or pedal arteries do not cause claudication, and interventions on these blood vessels for claudication are contraindicated.

103. For these reasons, for patients with claudication, it is reasonable to intervene on severe lesions in the femoropopliteal (above the knee) distribution, but treatment of tibial (below the knee) lesions is outside the standard of care. For patients with chronic limb-threatening ischemia, it is within the standard of care to intervene on any moderate stenosis in any anatomic distribution.

104. When intervention is clinically indicated based on the above criteria, appropriate invasive interventions can include atherectomy (the use of a sharp blade, burr, or laser at the end of a catheter to shave off plaques from within an artery), angioplasty (the use of a balloon that is inserted into and expanded within the artery to widen the space for blood to flow through); or the placement of a stent (a small metallic mesh tube placed inside a blocked or narrowed artery to keep the vessel open after it has been dilated after balloon angioplasty), either alone or in combination depending on the patient's needs. Invasive imaging such as an angiogram or intravenous ultrasound ("IVUS") may also be appropriate, depending on the patient's needs and the provider's clinical objective.

105. IVUS is an adjunct tool that is used to evaluate the arteries from the inside of the vessel. It is sometimes used for sizing a blood vessel prior to stent placement, or for evaluating for a complication such as dissection (tearing) of the

blood vessel after atherectomy or angioplasty. There is no data to support the use of routine IVUS for lower extremity interventions.

106. The applicable professional society guidelines set forth the appropriate use of atherectomy for lower extremity PAD, which is limited to applications of in-stent restenosis and highly calcific lesions. *See*, *e.g.*, Dmitri Feldman *et al.*, *SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions*, 92 Catheter Cardiovascular Interv. 124-140 (2018).

107. There are substantial data showing that atherectomy does not improve outcomes of lower extremity interventions compared to other procedures (which are reimbursed by Medicare at lower rates). To the contrary, this same data shows that atherectomy may in fact increase the risk of distal embolization and late amputation. These findings underscore the importance of following the applicable professional guidelines, that is, to perform this invasive measure only when: (1) other less risky measures have failed; (2) the cause of a patient's leg pain is due to PAD and no other comorbidity; and (3) the PAD is severely disabling an otherwise physically active patient.

108. Atherectomy, angioplasty, and stent implantation, as well as angiograms and the use of IVUS, are invasive procedures that usually require conscious sedation and subject patients to some risk of harm. For example, any invasive procedure can lead to "restenosis" or re-narrowing due to scar build-up at the site of intervention. The catheter can tear or rupture blood vessels causing internal bleeding. It can also dislodge plaques from the arterial wall that can travel

downstream or "embolize" into the circulation and lead to stroke, heart attack, or poor blood flow to a limb requiring major amputation. The dye injected into the arteries during a catheterization procedure can cause allergic reactions or kidney injury or failure. The radiation used for imaging can lead to injuries ranging from dermatitis to cancer.

109. Stents can trap or "jail" other arteries depending on their placement, sometimes cutting off important alternative avenues of collateral circulation. If dislodged, they can cause damage to other vessels or require major open surgery to retrieve them. Stents can also limit surgical options for revascularization. Excessive stenting can limit the number of viable, un-stented arteries into which a bypass can be connected.

110. Further, data confirms that these procedures carry risks beyond those posed by the complications that typically come with invasive interventions. In patients with intermittent claudication, the risk of limb loss within 5 years without intervention is 1% to 2%. However, if a claudication patient has an invasive procedure—including the atherectomy, angioplasty, stent placement, and IVUS procedures at issue here—their risk of limb loss within 5 years goes up to 5% to 10%. Vashisht Madabhushi *et al.*, *Revascularization of intermittent claudicants leads to more chronic limb-threatening ischemia and higher amputation rates*, 74 J. Vasc. Surg. 771-779 (2021). Medically unnecessary PAD procedures are thus not only a drain on taxpayer dollars; they put patients at unnecessary risk of serious and potentially permanent harm.

D. The Medicare Benefit for PAD

111. Medicare's highest reimbursement for PAD procedures is for multiple interventions billed in the same encounter. During the relevant period, the highest reimbursement rate was for the performance of three interventions—atherectomy, angioplasty, and the placement of a stent in the femoral region of the leg (above the knee)—in the same procedure, for which Medicare reimbursed providers approximately $15,000. *See* CPT Code 37227 (femoropopliteal atherectomy/ angioplasty/ stent). For atherectomy and angioplasty performed in the same procedure below the knee, Medicare reimbursed providers approximately $5,000. *See* CPT Code 37229 (tibial atherectomy/angioplasty). Medicare also reimbursed providers for the properly documented use of IVUS under CPT Codes 37252 and 37253 (for initial and subsequent uses of IVUS), at rates of approximately $1,200 and $190, respectively.

112. Eligibility for these high reimbursement rates requires providers to clinically establish and sufficiently document that each of the interventions were actually performed and were medically necessary under the applicable standards of care. Medicare providers are not entitled to bill or receive payment for any PAD procedure, including angioplasty, atherectomy, or stent implantation, or the use of IVUS, that is not "reasonable," and medically "necessary," 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 U.S.C. § 1320c-5(a)(l). Like any procedure, Medicare pays for angioplasty, atherectomy, stent implantation, and the use of IVUS, only "when, and to the extent," the provider's medical documentation establishes those

procedures as "medically necessary," were actually rendered, and "of a quality which meets professionally recognized standards of health care." 42 U.S.C. §§ 1320c-5(a)(l) and 5(a)(2); 42 U.S.C. § 1395y(a); 42 C.F.R. § 424.24(g)(1).

113. Even more specifically, and consistent with the standards of care described above, the applicable Local Coverage Determination states explicitly that stenting is appropriate (and reimbursable) in lower extremities only when the following conditions are met:

a. the patient demonstrates significant symptoms such as "lifestyle-limiting claudication, focal hemodynamically significant lesion, ischemic rest pain, non-healing tissue ulceration and focal gangrene;"

b. the patient has had a thorough evaluation and treatment of symptoms;

c. angioplasty of the vessel alone has not, or is not expected to, sufficiently resolve the symptoms, making surgery the likely alternative;

d. The submitted medical record "support[s] the use of the selected ICD-10-CM code(s)" and "the medical necessity of the services;" and

e. The provider's documentation "reflect[s] an effort to establish a cause-and-effect relationship between the lesion to be treated and the presenting symptoms or other objective findings (e.g., hypertension secondary to renal artery stenosis versus essential hypertension with incidental renal stenosis)."

See Local Coverage Determination (LCD): Non-Coronary Vascular Stents (L35084). The LCD similarly confirms the more exacting standards of care for procedures performed in the lower parts of the leg. The LCD expressly cautions that stent placement in infrapopliteal (below the back of the knee) vessels is "not expected to

be often indicated and in those cases the rationale for stent placement must be explained in the record." *Id.*

114. Further, while the LCD allows for sequential procedures to be performed in a single encounter (such as atherectomy followed by an angioplasty followed by the placement of a stent), each procedure is appropriate (and reimbursable) *only* if the "initial approach was unsuccessful or only partially successful in accomplishing the intended goal (that is, to maintain or re-establish the patency of a vessel)." (Emphasis added). *See also* NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7) (providing that coverage of angioplasty with stenting not specifically addressed or discussed therein is at local MAC discretion).

115. As a general principle, "[e]ndovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD." *See* Jeffrey L. Anderson, *et al.*, "Management of Patients with Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations)," Journal of the American College of Cardiology, Vol. 61, No. 14 (Apr. 2013). Thus, prior to performing an interventional procedure in the peripheral arteries, Medicare providers must assess the medical necessity of the intervention through a detailed evaluation, and thoroughly document the clinical indications necessitating the intervention.

116. In general, only after a Medicare provider has exhausted non-invasive tests and treatments—and after symptoms prove to be recurrent and disabling—should invasive procedures be performed on patients with severe PAD. "Disabling

refers to disabling in everyday life; although reported by the patient, the assumption was also that a thorough discussion had occurred and that the clinician agreed with the patient regarding the degree of lifestyle limitation. Thus, the clinician must have explained, in detail, the rationale that the limitation must be severe enough to justify the risks associated with treatment to help guide patients in reporting their limitations accurately." Karen Woo *et al.*, *Society for Vascular Surgery appropriate use criteria for management of intermittent claudication*. 76 J. Vasc. Surg. 3-22 (2022).

> Given that PAD and [intermittent claudication] typically occur in later stages of life (beyond the age of 60 years), common comorbidities such as arthritis and heart and lung diseases may contribute significantly to loss of function and would therefore limit the potential benefit (and increase the risk) of vascular interventions . . . The optimal selection of candidates for invasive therapy in IC should hinge first and foremost on the estimate of disease-specific disability, a lack of improvement with first-line measures (medical therapy, exercise), and an individualized risk-benefit analysis for the interventions under consideration.

Michael S. Conte, *Data, guidelines, and practice of revascularization for claudication*, 66 J. Vasc. Surg. 911-915 (2017). Patients who are robust, independently functional, and have a greater than 5-year life expectancy are considered low risk for invasive interventions for intermittent claudication. Patients who are frail, completely dependent, or have a less than 2-year life expectancy are considered high-risk for invasive interventions for intermittent claudication. *See* Karen Woo *et al.*, *Society for Vascular Surgery appropriate use criteria for management of intermittent claudication*. 76 J. Vasc. Surg. 3-22 (2022).

V. DEFENDANTS SUBMITTED FALSE CLAIMS FOR EXCESSIVE, MEDICALLY UNNECESSARY PAD PROCEDURES.

117. Throughout the relevant period, Defendants engaged in a pattern and practice of subjecting patients to unnecessary, invasive, and potentially harmful interventions for the sole purpose of billing Medicare for the highest reimbursements available.

118. Witnesses, documents from McGuckin and his practices, objective billing data, and an examination of a sample of McGuckin's patient medical files all confirm a consistent scheme: McGuckin put profits over the health and safety of his patients and performed procedures that earned the highest rate of reimbursement regardless of patient symptoms or need.

119. Defendants' conduct resulted in the submission of thousands of false claims to Medicare for medically unnecessary invasive vascular procedures.

A. McGuckin's Singular Focus on Profits over Patient Need

120. In McGuckin's own words, "[m]y centers are low volume, high revenue." McGuckin May 1, 2017 Dep. Tr., 157:15-17.

121. Minutes from Defendants' board meetings document their singular focus on increasing the number of high-reimbursement procedures performed, setting monthly goals of 20 PAD procedures per month.

122. McGuckin pressured physicians to increase their patient "acuity"—meaning "revenue"—by performing procedures reimbursed at a higher rate than the ones they thought were appropriate for their patient.

123. To generate high-reimbursement PAD patients, McGuckin would instruct physicians in his practices to screen all dialysis patients for PAD. McGuckin made clear that his reason for this instruction was not based on patient need, but instead was purely financial: he warned the physicians in his practices that "every [end-stage renal disease] patient not assessed for PAD in both History and Physical Examination pushes your center, including you and your staff, towards the edge of insolvency." McGuckin letter to PVI physicians, Sept. 17, 2018.

124. McGuckin also instructed physicians to perform IVUS on every Medicare patient instead of using less invasive diagnostics and regardless of patient need, for no reason other than to be able to bill Medicare for the use of the device. "IVUS is an ATM," he said.

125. MLVI board meeting minutes from June 2019 confirm IVUS was used in every patient as a preliminary diagnostic tool and regardless of need: "All patient procedures allowing receive a diagnostic IVUS to indicate disease." There is currently no data supporting such a routine use of IVUS for lower extremity interventions, and no standard of care supports the indiscriminate use of the invasive technology.

126. To remind physicians to use IVUS on all patients, Defendants' employees would set out the IVUS device and materials when prepping all PAD patients for procedures, regardless of the physician's determination of patient need.

127. Defendants engaged in systematic fishing expeditions to find arteries to treat. Defendants scheduled follow up tests of largely asymptomatic patients at

regular intervals established by McGuckin—sometimes every 6 months and sometimes in a matter of mere days. The follow up tests included invasive, but lucrative, angiography, and other expensive procedures. Most were done without any prior noninvasive imaging or other indication justifying these invasive procedures. Patients that McGuckin performed an angiogram on in one leg routinely were brought back for an angiogram of both legs within a few weeks, regardless of indication.

128. To convince patients to undergo these painful, inconvenient, and risky invasive procedures, McGuckin would tell them that the procedures were necessary to "save their leg"—or, more crassly, "stop the chop." McGuckin's representations were directly contrary to national practice guidelines that such procedures should not be performed in patients with PAD solely to prevent progression of the disease to a point where amputation might be a possibility.

129. One former patient stated that he was not happy with McGuckin's care; he said that McGuckin performed so many procedures on his legs that at times it felt like McGuckin "was just experimenting on him."

130. Consistent with his scheme to perform as many high-reimbursement invasive procedures as possible without regard to patient need or safety, McGuckin traveled the state to perform these procedures on any patients he could find, but did not stay long enough to ensure his patients recovered from the procedures or to address any post-operative complications. Instead, he told members of his practices

who do not regularly perform these procedures to "deal with it" or left patients to seek emergent follow-up care at local emergency departments.

B. McGuckin's Records Demonstrate Inadequate Patient Assessment and Symptoms to Support the Medical Necessity of the Invasive Procedures He Performed.

131. McGuckin's medical records reflect the excessiveness and underlying lack of medical necessity of the invasive procedures he performed.

132. As reflected in the records, Defendants regularly failed, for example, to properly assess relevant medical histories and symptoms supporting invasive treatments, including debilitating claudication and chronic limb-threatening ischemia.

133. Similarly, Defendants often failed to exhaust non-invasive treatments before conducting peripheral artery interventions.

134. Defendants' patient records lack evidence that any of the patients McGuckin performed invasive procedures on underwent any preoperative medical management for PAD or related symptoms, as required by the applicable standards of care

135. McGuckin and his staff also did not evaluate patients preoperatively. His preoperative reports include only a cursory review and exam and no indication he evaluated the symptoms or studies that would lead to intervention.

136. Generic, non-specific, summary terms for PAD and IVUS found in the medical records do not by themselves support a need for intervention. One patient's record notes little more than that the patient, "a[n] 85 year old male[,] is here to

have a[n] interventional Arteriogram." Another's merely recites, in cursory fashion, "Intra-vascular ultrasound was performed of the Left Iliacs, Left SFA, and Left Anterior Tibial Artery was performed[sic]."

137. The pre-procedure diagnosis on almost all operative reports from McGuckin cites, "stricture of artery, [bilateral/right/left] calf claudication" as the indication for intervention, which are generic, non-specific summary terms for PAD that do not, alone, support a need for intervention.

138. A review of his records confirms that when tests revealed stenosis in patients' arteries, McGuckin often overestimated the severity of the blockage to justify lucrative interventions, including angioplasty, atherectomy, and stent implantation.

139. This review further confirmed McGuckin's regular practice of bringing patients who had an angiogram on one leg back to have an angiogram of both legs within a matter of weeks, regardless of any indication for the need for such invasive procedures.

140. Defendants' gross overutilization of Medicare services for this vulnerable population significantly deviated from what other vascular specialists—and Medicare—consider reasonable and appropriate.

141. A review of Defendants' records also confirms that in some cases, McGuckin billed Medicare for procedures with no evidence he performed these procedures at all.

C. Defendants' False Claims for McGuckin's Excessive, Medically Unnecessary Procedures

142. An expert review of a statistically valid random sample of claims for certain PAD procedures performed by McGuckin confirmed that, in order to maximize reimbursement, McGuckin would perform atherectomy, angioplasty, and stent on nearly every PAD patient: (1) regardless of symptoms (or lack of symptoms); (2) without any assessment of need; (3) without first attempting non-surgical measures (exercise, medication); and (4) without making any assessment of the sufficiency of any of these measures alone, in contravention of the standard of care and Medicare's reimbursement requirements. These records similarly confirm that McGuckin used IVUS on virtually every PAD patient for no apparent purpose.

143. The false claims set forth below are specific examples, drawn from a statistically valid random sample of claims Defendants submitted to Medicare for CPT Codes 37227 (femoropopliteal atherectomy/angioplasty/stent), 37229 (tibial atherectomy/angioplasty), 37252 (initial use of IVUS) and 37253 (subsequent use of IVUS), of the false claims that Defendants submitted to Medicare throughout the relevant period.[3]

Patient TT, Claim Date June 18, 2019

144. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on TT, a 72 year-old Medicare beneficiary, on June 18, 2019.

[3] To protect their privacy, the Medicare beneficiaries discussed herein are identified by their first and last initials.

145. On June 18, 2019, McGuckin performed a right lower extremity angiogram with atherectomy/stent of the superficial femoral artery, and also stated he performed an atherectomy of a tibial artery. McGuckin billed Medicare for femoropopliteal atherectomy/stent (CPT 37227), tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) on this date of service.

146. McGuckin reported the indication for these interventions as "stricture of artery, right leg claudication." However, a note in TT's medical chart from May 4, 2019 documents that she has left hemiplegia due to prior stroke and dementia, and is incapacitated. A later note from October 25, 2019 confirms her inability to walk due to her paralysis and dementia, and that she mostly stays in bed all day. As such, it was unlikely Patient TT was able to experience claudication (since she was not walking at all), and her alleged PAD was not the cause of any lifestyle-limiting disability. Based on this information, Patient TT could not have been suffering from claudication or PAD-related disability sufficient to justify intervention, and the intervention performed by McGuckin on June 18, 2019 was not medically necessary.

147. While there is imaging of femoropopliteal atherectomy and stent placement, as well as below-knee popliteal atherectomy and balloon angioplasty, there is no imaging documenting a tibial intervention of any kind.

148. While McGuckin billed Medicare for multiple uses of IVUS on Patient TT on this date of service, there is no documentation that IVUS was performed. McGuckin provided no IVUS images to document it was used, nor did he specify in his record the vessel(s) visualized or the relevant findings. He simply recited in the

impression of the radiographic report that "IVUS was performed." There is no record substantiating the medical necessity of the use of IVUS.

149. While there is a record that Patient TT may have had left toe gangrene for which some left-sided intervention on June 4, 2019 was likely warranted, there is no justification evident in the record for McGuckin's multiple evaluations of and invasive procedures on Patient TT's right side at all.

150. There is no evidence that McGuckin or his team conducted any of the non-invasive measures indicated for any symptoms Patient TT was reportedly experiencing on her right side before performing these invasive procedures.

151. While not on the date of service evaluated as a part of the sample, it is notable that Patient TT underwent three subsequent angiograms by McGuckin on June 18, 2019 (a mere two weeks following her June 4, 2019 procedures), December 4, 2019, and May 19, 2020. The above documentation suggests each of these invasive diagnostic procedures were similarly performed without any medical justification and were therefore not medically necessary.

152. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient TT on June 18, 2019. *See* Ex. A.

Patient OC, Claim Date June 13, 2018

153. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient OC, a 78 year-old Medicare beneficiary, on June 13, 2018.

154. On June 13, 2018, McGuckin performed a right lower extremity angiogram on Patient OC for the reported indication of "stricture of artery, bilateral calf claudication." McGuckin billed Medicare for femoropopliteal atherectomy/ angioplasty/stent (CPT 37227) and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on Patient OC on this date of service.

155. Patient OC was evaluated by Dr. Arnold for in-home cardiac rehabilitation on May 16, 2018, less than one month before the procedure. Dr. Arnold reported that while Patient OC has history of PAD (including a left toe amputation and stent placement) in 2015, "since that procedure, [OC] has had no recurrence of intermittent claudication." Dr. Arnold further confirmed that on physical exam, "there is no evidence of distal cyanosis of the toes or active ulceration." A subsequent duplex ultrasound on the same day of Arnold's note showed mild superficial femoral artery stenosis, for which he was referred for invasive intervention. Based on this information, Patient OC had asymptomatic PAD, and the invasive interventions performed by McGuckin on June 13, 2018 were not medically necessary.

156. While McGuckin billed Medicare for multiple uses of IVUS on Patient OC on this date of service, he stated no indication for IVUS. He simply recited in

the impression of the radiographic report that "Intravascular ultrasound was performed of the right SFA and the right Posterior Tibial, and bilateral Iliac artery regions." There is no record substantiating the medical necessity of the use of IVUS.

157. Despite Dr. Arnold's note documenting "no recurrence of intermittent claudication," Patient OC underwent a bilateral lower extremity duplex. Although this duplex showed possible stenoses, Patient OC demonstrated no symptoms of PAD. Invasive interventions for asymptomatic PAD are never indicated.

158. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient OC on June 13, 2018. *See* Ex. A.

Patient SK, Claim Date February 22, 2016

159. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on patient SK, a 67 year-old Medicare beneficiary, on February 22, 2016.

160. On February 22, 2016, McGuckin performed a right lower extremity angiogram on SK for the reported indication of "stricture of artery, right sided claudication." McGuckin billed Medicare for femoropopliteal atherectomy/ angioplasty/stent (CPT 37227) and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on SK on this date of service.

161. SK's medical records included a number of non-invasive studies (ABIs or duplex), but none of her right leg perfusion prior to intervention. Her last ABIs

that included right-sided data were performed on May 7, 2015. While these studies noted an occlusion of the proximal superficial artery with reconstitution of the mid superficial femoral artery, her distal toe pressures were normal. Further, Dr. Jay Fisher noted in Patient SK's indication for the bilateral lower extremity duplex performed on May 7, 2015 that "she is able to walk very far before leg pain begins." While McGuckin ordered additional duplex imaging of Patient SK's heart and left leg on February 15, 2016, he obtained no additional non-invasive imaging of SK's right leg prior to performing the invasive angiogram more than 9 months later. Nor are there any updated notes to reflect worsening symptoms of claudication. Based on this information, SK was not appropriately worked up with either imaging or a physical exam prior to her procedure, and the intervention performed by McGuckin on February 22, 2016 was not medically necessary.

162. McGuckin provided no documentation on the non-invasive management of Patient SK's PAD. According to a note from Dr. Kristin Marek (Broadheadsville Family Practice) on December 4, 2015, Patient SK was actively smoking and not prescribed a statin. There is no mention of discussing supervised exercise therapy or other exercise with the patient prior to her intervention. Smoking cessation, statin therapy, and a standardized walking program are first-line treatments for PAD.

163. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or

inadequately documented interventions performed on Patient SK on February 22, 2016. *See* Ex. A.

Patient LS, Claim Date April 29, 2019

164. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient LS, a 93 year-old Medicare beneficiary, on April 29, 2019.

165. On April 29, 2019, McGuckin performed a right lower extremity angiogram on Patient LS for a right toe wound, and femoropopliteal atherectomy and angioplasty. McGuckin billed Medicare for tibial atherectomy (CPT 37229) and multiple uses of IVUS (CPT 37252, 37253) on this date of service.

166. There is nothing in the medical records showing that McGuckin performed any tibial procedure.

167. In his operative report, McGukin noted a 70% stenosis in the right superficial femoral artery, which he treated with an atherectomy and stent. However, Patient LS's imaging shows that her superficial femoral artery and popliteal artery appear widely open with no evidence of moderate or severe stenosis that might justify any intervention under the applicable standards of care. The intervention performed by McGuckin on April 29, 2019 was not medically necessary.

168. While McGuckin billed Medicare for multiple uses of IVUS on Patient LS on this date of service, there is no documentation that IVUS was performed. McGuckin provided no IVUS images to document it was used, nor did he specify in

his record the vessel(s) visualized or the relevant findings. He simply recited in the impression of the radiographic report that "Right SFA, AT, PT, and Peroneal intravascular ultrasound was performed." There is no record substantiating the medical necessity of the use of IVUS.

169. Patient SK was noted to have cuts on her right foot in a physical exam performed during an emergency room visit for a fall on February 7, 2019. A right lower extremity duplex was performed on April 1, 2019, the results of which confirmed Patient SK had "adequate wound healing potential in the right limb." Despite this finding, McGuckin subsequently performed a right lower extremity angiogram on April 19, 2019. He did so despite Patient SK having a code status of DNR/DNI (do not resuscitate/do not intubate, indicating life expectancy is very low) as of February 7, 2019, making her extremely high risk for an invasive intervention.

170. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient LS on April 29, 2019. *See* Ex. A.

Patient RS, Claim Date August 13, 2019

171. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient RS, a 74 year-old Medicare beneficiary, on August 13, 2019.

172. On August 13, 2019, McGuckin performed a left lower extremity angiogram on RS, followed by a femoral atherectomy and placement of a stent.

McGuckin billed Medicare for femoropopliteal atherectomy/angioplasty/stent (CPT 37227) and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on Patient RS on this date of service

173. In his operative report, McGuckin noted that Patient RS had an 85% calcific eccentric stenosis in her left SFA, requiring multiple interventions, including atherectomy, stent, and repeat angioplasties. To the contrary, Patient RS's imaging confirms there was minimal superficial femoral artery disease with no flow-limiting lesions that might necessitate any intervention under the applicable standards of care. The interventions performed by McGuckin on August 13, 2019 were not medically necessary.

174. While McGuckin billed Medicare for multiple uses of IVUS on Patient RS on this date of service, there is no documentation that IVUS was performed. McGuckin provided no IVUS images to document it was used, nor did he specify in his record the vessel(s) visualized or the relevant findings. He simply recited in the impression of the radiographic report that "Intra-vascular ultrasound of the bilateral iliac arteries, Left SFA, AT, and PT arteries was performed." There is no record substantiating the medical necessity of the use of IVUS.

175. Patient RS underwent evaluation with an aortoiliac duplex on April 26, 2018 that demonstrated no evidence of stenosis of the bilateral common iliac artery stents and the bilateral external iliac arteries. He also underwent ABI and bilateral lower extremity duplex testing on May 15, 2019 that showed "the right ankle/brachial index of 1.08 is *in the normal range*," and arteries that were widely

open, "without evidence of stenosis," and with "no significant narrowing." (Emphasis added). McGuckin obtained no other imaging prior to conducting an angiogram on August 13, 2019. The records indicate McGuckin performed the angiogram for only "mild atherosclerotic disease," which was medically unnecessary.

176. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient RS on August 13, 2019. *See* Ex. A.

Patient EK, Claim Date May 24, 2019

177. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient EK, a 73 year-old Medicare beneficiary, on May 24, 2019.

178. On May 24, 2019, McGuckin performed a right lower extremity angiogram on EK with a distal anterior tibial/dorsalis pedis atherectomy and angioplasty. McGuckin billed Medicare for tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) on this date of service.

179. In his operative report, McGuckin noted that "[t]he right anterior tibial artery was selectively catheterized and the 100% stenosis of the dorsalis pedis artery was thrombectomized followed by residual stenosis being was with 2.0mmx38mm PTA after orbital atherectomy." However, Patient EK's imaging shows there was a widely open anterior tibial and dorsalis pedis artery, such that

no intervention was indicated under the applicable standards of care. The intervention performed by McGuckin on May 24, 2019 was not medically necessary.

180. While McGuckin billed Medicare for multiple uses of IVUS on Patient EK on this date of service, he did not state the indication for IVUS. He simply recited in the impression of the radiographic report that "[t]he iliac system, the Iliac arteries bilaterally, Right SFA, and Right Anterior Tibial were studied with IVUS." There is no record substantiating the medical necessity of the use of IVUS.

181. Patient EK had right foot ulcers at the time of his right lower extremity angiogram on May 24, 2019. While PAD with ulcers is an indication for intervention, the presence of ulcers alone is not. PAD must be documented as being present; patients with diabetes (as Patient EK had) often develop ulcers due to neuropathy that is not related to PAD. No non-invasive studies were performed prior to Patient EK's angiogram on May 24, 2019, and his angiogram images show no significant narrowing or blockages in the arteries of the right leg. The angiogram was a medically unnecessary procedure and would have been avoided had appropriate preoperative testing been performed.

182. While not on the date of service evaluated as a part of the sample, it is notable that Patient EK, having undergone the angiogram on his lower right leg for a foot ulcer on May 24, 2019 (which itself, for the reasons above, was not indicated), underwent a subsequent angiogram of his lower *left* leg by McGuckin less than two weeks later, for no apparent reason at all. This subsequent angiogram was similarly

performed without any medical justification and was therefore not medically necessary.

183. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient EK on May 24, 2019. *See* Ex. A.

Patient OE, Claim Date February 7, 2018

184. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient OE, a 54 year-old Medicare beneficiary, on February 7, 2018.

185. McGuckin billed Medicare for a right lower extremity angiogram with femoropopliteal atherectomy/stent (CPT 37227), tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on Patient OE on this date of service. However, there is no operative report for this intervention. Despite billing Medicare for a femoropopliteal atherectomy and stent placement, there is no operative note or imaging documentation demonstrating that either intervention was actually performed.

186. Further, Patient OE's imaging shows he had a widely open superficial femoral artery with no evidence of disease, a widely open popliteal stent, and runoff via widely open posterior tibial and peroneal arteries, such that no femoral or tibial intervention was necessary within the applicable standards of care.

187. While McGuckin billed Medicare for multiple uses of IVUS on Patient OE on this date of service, there is no documentation that IVUS was performed. McGuckin provided no IVUS images to document it was used, nor did he provide an operative report. There is no record substantiating the medical necessity of the use of IVUS.

188. Patient OE had a right great toe ulcer at the time of his right lower extremity angiogram on February 7, 2018. While PAD with ulcers is an indication for intervention, the presence of ulcers alone is not. No non-invasive studies were performed prior to Patient OE's angiogram on February 7, 2018. In addition, Patient OE was not on a statin at the time of his intervention despite having had multiple angiogram procedures in the past.

189. There is no imaging or operative note documentation that McGuckin actually performed the femoropopliteal atherectomy and stent placement or IVUS interventions he billed Medicare for on February 7, 2018; to the extent he did perform these interventions, they were not medically necessary.

190. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient OE on February 7, 2018. *See* Ex. A.

Patient JB, Claim Date March 8, 2019

191. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on patient JB, a 70 year-old Medicare beneficiary, on March 8, 2019.

192. McGuckin performed a left lower extremity angiogram on Patient JB McGuckin on 3/8/2019. McGuckin billed Medicare for femoropopliteal atherectomy/stent (CPT 37227), tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) on this date of service.

193. In his operative report, McGuckin documented a left superficial femoral artery atherectomy and two stent placements, as well as bilateral iliac, right SFA, and peroneal IVUS.

194. However, there is no evidence a tibial atherectomy was performed. Tibial atherectomy is not documented in the operative report, and not present on imaging. The tibial atherectomy code was billed incorrectly based on the documentation provided.

195. While McGuckin billed Medicare for multiple uses of IVUS on Patient JB on this date of service, he did not state the indication for IVUS. McGuckin simply recited in the impression of the radiographic report that "Bilaterial Iliac, Right SFA, and Peroneal Intra-vascular ultrasound was performed." There is no record substantiating the medical necessity of the use of IVUS.

196. Patient JB had a left web space ulcer at the time of his left lower extremity angiogram on March 8, 2019. While PAD with ulcers is an indication for

intervention, the presence of ulcers alone is not. A bilateral lower extremity duplex ultrasound performed on February 13, 2019 demonstrated a left "great toe pressure 86 mmHg, within the healing range."

197. Patient JB also underwent a right lower extremity angiogram within two weeks of his left leg procedure on March 15, 2019, also for no documented indication. A bilateral lower extremity duplex ultrasound performed on February 13, 2019 demonstrated a right "great toe pressure of 80 mmHg, within the healing range."

198. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient JB on March 8, 2019. See Ex. A.

Patient LW, Claim Date June 21, 2018

199. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on patient LW, a 70 year-old Medicare beneficiary, on June 21, 2018.

200. McGuckin billed Medicare for femoropopliteal atherectomy/stent (CPT 37227), tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on Patient LW on June 21, 2018.

201. In his operative report, McGuckin cited "claudication" as the basis for his invasive tibial interventions on Patient LW. Professional guidelines caution that claudication does not justify an invasive measure in the tibial region of the leg, and

there are no other indications in the record that this invasive measure was medically necessary.

202. While McGuckin billed Medicare for multiple uses of IVUS on Patient LW on this date of service, he did not state the indication for IVUS. He simply recited in the impression of the radiographic report that "Right SFA, AT, and Bilateral Iliac arteries were studied via Intra-vascular ultrasound was performed." There is no record substantiating the medical necessity of the use of IVUS.

203. A bilateral duplex ultrasound on February 22, 2018 documented "severely abnormal waveforms of the right distal femoral artery." However, Patient LW had no symptoms related to this finding. Based on a cardiac consult note dated February 6, 2018, Patient LW "does ambulate throughout his home with a 4-pronged front wheeled walker. For outings, he does utilize a manual wheelchair." It is highly unlikely that he was experiencing symptoms of claudication (the indication for his right lower extremity angiogram) given that he was non-ambulatory. In his own perioperative documentation, McGuckin noted Patient LW was "disabled." In addition, Patient LW had a notable history of heart failure, cardiomyopathy, coronary artery disease, and end stage renal disease with dyspnea on mild-to-moderate exertion, making him extremely high risk for an elective invasive procedure.

204. Patient LW underwent additional invasive angiograms on September 20, 2018, April 4, 2019, and May 16, 2019, none of which have a documented indication for intervention.

205. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or inadequately documented interventions performed on Patient LW on June 21, 2018. *See* Ex. A.

Patient BM, Claim Date September 16, 2019

206. Defendants knowingly submitted or caused the submission of false claims for PAD interventions performed on Patient BM, a 53 year-old Medicare beneficiary, on September 16, 2019.

207. McGuckin performed a left lower extremity angiogram on Patient BM on September 16, 2019. McGuckin billed Medicare for femoropopliteal atherectomy/angioplasty/stent (CPT 37227), tibial atherectomy (CPT 37229), and multiple uses of IVUS (CPT 37252, 37253) for procedures allegedly performed on Patient BM on this date of service.

208. Patient BM presented to McGuckin with a prior left below-the-knee amputation (BKA) from July 2018. A BKA means an amputation through the lower leg at approximately the level of the mid-calf. Below-the-knee interventions for PAD are rarely indicated in any circumstance and are even less likely to be indicated in cases where almost no tibial portion of the leg remains. There may be rare instances in which a femoropopliteal intervention is required in a BKA patient (*e.g.*, in a patient with a non-healing BKA wound), but claudication is not a known symptom in a BKA and any tibial intervention is nearly impossible as the tibial vessels are all ligated.

209. On September 6, 2019, McGuckin performed a left lower extremity angiogram on Patient BM for "left calf claudication." His records for these procedures lack evidence he made any assessment of whether Patient BM's alleged left calf pain with walking was due to PAD or some other source (such as a prosthetic).

210. McGuckin's operative report from September 6, 2019 documented a left SFA stenosis that was treated with an orbital atherectomy and stent, as well as a peroneal and anterior tibial orbital atherectomy for 70% stenosis, and IVUS of the SFA, peroneal, and anterior tibial arteries. There is no record substantiating the medical necessity of any tibial intervention on Patient BM's residual limb, nor were any such invasive interventions necessary under the applicable standards of care.

211. While McGuckin billed Medicare for multiple uses of IVUS on Patient BM on this date of service, he stated no indication for IVUS. He simply recited in the impression of the radiographic report that "IVUS of Left SFA, Anterior Tibial, and Peroneal arteries was performed." There is no record substantiating the medical necessity of the use of IVUS.

212. There are no non-invasive imaging studies of the left leg to substantiate an invasive intervention. Lower extremity ultrasound studies performed on May 31, 2019 report blood flow measures only for the right leg.

213. Defendants were not entitled to receive Medicare payments for the false claims Defendants submitted for excessive, medically unnecessary, and/or

inadequately documented interventions performed on Patient BM on September 16, 2019. *See* Ex. A.

D. McGuckin is an Extreme Outlier Compared to Other Doctors Performing PAD Procedures.

214. Data confirms that McGuckin is an "extreme outlier" among PAD practitioners (including interventional radiologists and vascular surgeons) nationwide.

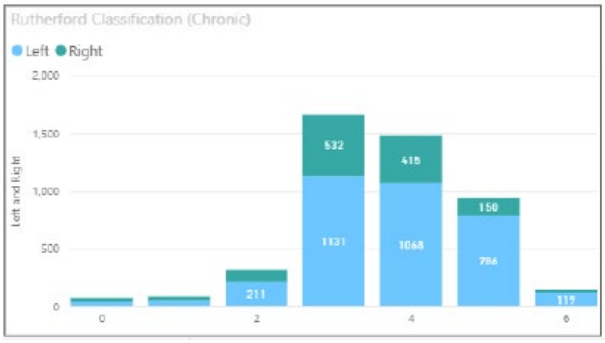
215. For the years 2016-2020, despite having an average practice size and number of patients, McGuckin was ninth out of over 6,500 practitioners in Medicare Part B reimbursements for the four codes examined in the government's statistical analysis (CPT 37227; CPT 37229; CPT 37252; 37253). He was thirteenth in number of beneficiaries billed for the codes at issue. For amounts paid for these codes, he was second highest in the country. He was fourth in the country in the number of these procedures performed. In Pennsylvania, McGuckin was first in nearly all of these categories.

216. Based on an analysis of 100% fee-for-service Medicare claims in 2019, McGuckin was an outlier in both his use of atherectomy and IVUS during invasive interventions for claudication. He used atherectomy in 100% and IVUS in 86.1% of his claudication cases in 2019. Outliers for this time period were defined as the upper quartile of users, equivalent to greater than or equal to 85% for atherectomy use and greater than or equal to 80.2% for IVUS. McGuckin exceeds both measures.

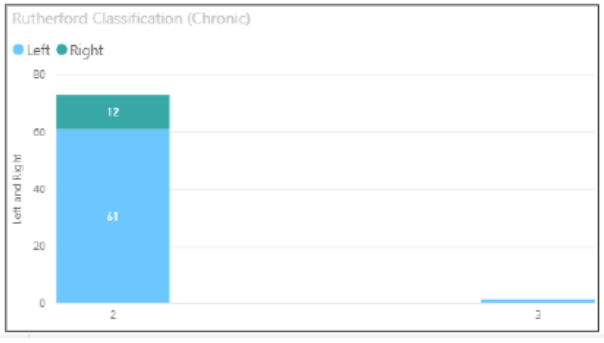
217. His practices fare little better: PVIP and PAVI are themselves outliers on CPT Codes 37227 and 37252.

218. Perhaps most objectively indicative of McGuckin's performance of medically unnecessary invasive PAD procedures is his own self-reporting to the OEIS National Qualified Clinical Data Registry—a voluntary registry where providers of office-based PAD interventions can share their data, and which, according to McGuckin, is also used for CMS Quality Reporting. Among other data, practitioners report the severity of their patient's PAD at the time of intervention based on the Rutherford Classification for Chronic Disease, rating their patients on a scale from Rutherford 0 (asymptomatic) to 6 (indicating major tissue loss and irreparable disease).

219. The nationally reported data shows that clinicians nationwide perform invasive procedures generally only on patients measuring Rutherford 3 (severe claudication), 4 (ischemic rest pain), or 5 (tissue loss, non-healing ulcers, and focal gangrene). McGuckin reports performing nearly all of these procedures on patients measured as Rutherford 2—only "moderate claudication"—in direct contravention of all practice guidelines and standards of care.



OEIS 2021 National Registry Summary, All MDs



OEIS 2021 National Registry Summary, McGuckin

E. Defendants Knew the Certifications and Claims they Submitted to Medicare Were False.

220. Throughout the relevant period, Defendants knew that their certifications and claims for reimbursement submitted to Medicare were false, or else deliberately ignored or were recklessly indifferent to, the truth or falsity of those certifications and claims.

221. McGuckin has admitted in writing to, and been personally sanctioned for, conducting invasive vascular procedures, including angioplasty and stenting, without first conducting the required patient assessments to ensure the procedures were medically necessary, and without proper documentation of the same. He has also confirmed in writing and under oath his personal knowledge that submitting a claim to Medicare that is not sufficiently documented as being medically necessary is a false claim subject to damages and penalties under the FCA.

1. McGuckin's 2015 Sanction by the Washington Medical Quality Insurance Commission

222. In 2015, McGuckin was investigated and sanctioned by the Washington Medical Quality Insurance Commission for performing experimental vascular procedures, including angioplasty and stenting, on hundreds of patients for the purported treatment of Multiple Sclerosis—a *non-vascular* disease. The Commission found that McGuckin performed the procedure on 233 patients in Washington between 2010 and 2013, and in performing those procedures: engaged in unprofessional conduct; created an unreasonable risk of harm for his patients; and failed to meet the basic standard of patient care.

223. In the 2015 Consent Decree he executed to resolve the investigation, McGuckin admitted performing vascular procedures "without proper patient assessment and accurate procedure notes." *See* Stipulated Findings of Fact, Conclusions of Law and Agreed Order at ¶2.11, available at https://www.njconsumeraffairs.gov/Actions/20170911_25MA05182900.pdf. McGuckin specifically admitted, among other things:

- Performing angioplasty and stenting on these patients without conducting the comprehensive patient intake process required, including obtaining and reviewing patient examination records from their referring neurologist;
- Performing these invasive procedures without conducting adequate physical evaluations of patients before the invasive procedures, or after;
- Diagnosing patients with conditions that might qualify them for intervention "without corroborating reports or exams;"
- In his procedure reports, reporting stenoses to be more severe than those seen in the relevant imaging;
- Performing interventions on abnormalities "that would not be considered significant or justified in requiring endovascular treatment."

224. As sanction for his admitted misconduct, including his failure to both ensure and document that the procedures he performed were medically necessary, the Commission ordered McGuckin to stop performing the procedure, refund his patients, pay a $17,500 fine, and take and pass an ethics course. McGuckin failed the ethics course twice and only passed after taking the course with the help of a one-on-one tutor.

225. Subsequent to the Commission's decision, medical boards in Florida, Illinois, North Carolina, Pennsylvania, California, Georgia, and New Jersey all took disciplinary action against McGuckin. As a result of this action, McGuckin is now excluded from Medicaid programs in Pennsylvania, Maryland, and elsewhere.

2. McGuckin's 2018 Resolution of Two Prior *Qui Tam* Lawsuits under the FCA

226. McGuckin and his practices have been the subject of multiple *qui tam* lawsuits alleging they submitted false claims to Medicare for medically unnecessary and insufficiently documented vascular procedures in violation of the FCA. *See United States ex rel. Levine v. Vascular Access Centers, L.P., et al.*, No. 12-cv-5103 (S.D.N.Y. 2012), and *United States ex rel. Boogaerts, et al. v. Vascular Access Centers, L.P., et al.,* No. 2:17-cv-02786-EEF-KWR (E.D. La. 2017). The relators in these actions, former employees of another collection of vascular practices in which McGuckin had an ownership interest through Vascular Access Centers, LP (the "VAC entities"), alleged that McGuckin and the VAC entities billed Medicare for vascular procedures on beneficiaries with end-stage renal disease, including angioplasties, without the required documentation of the medical necessity of these procedures.

227. In October 2018, McGuckin signed a settlement agreement admitting that the VAC entities regularly scheduled, performed, and billed for procedures "even though the patients presented without any documented evidence that they exhibited a need for therapies." *See* Settlement Agreement in *U.S. ex rel. Levine v.*

Vascular Access Centers, L.P., et al., No. 12-cv-5103, ECF No. 28 (S.D.N.Y. Oct. 9, 2018), at ¶ 2k.

228. While these prior *qui tam* lawsuits suits focused on different vascular procedures (for end-stage renal disease rather than PAD) and different McGuckin entities (the VAC entities, not the Defendant practices here), McGuckin's statements in these actions confirm his awareness that a failure to assess a patient's demonstrated need for the procedure in such a way that Medicare can confirm the medical necessity of the procedure subjects him to liability under the FCA.

229. In his May 1, 2017 deposition in a derivative action brought against him by his limited partners in the VAC entities, McGuckin admitted that insufficient documentation was a serious issue in his practices that he and his practices failed to correct. "Our [the VCA entities'] doctors are such knuckleheads they poorly documented the cases that they were doing." Tr. 184:14-16. He also admitted he is aware that the medical necessity of a procedure (and evidence to support the same) is material to Medicare's payment decision, and a failure to establish medical necessity renders the claim billed for that procedure false under the FCA:

> [The SDNY *qui tam* suit investigation is] saying because we didn't document perfectly that it's fraudulent billing. So even though the case merited it from a medical perspective, but *if you don't document it from an EMR, electronic medical record perspective, or if you don't document it from a patient history perspective or complaint perspective that warranted the case, then it's considered fraudulent billing. And I know obviously that it will bring the entire house down*. So I'm actively negotiating

> with JD [Barnea, the Assistant U.S. Attorney handling the SDNY *qui tam*].

Tr. 184:4-13 (emphasis added).

> *[B]etween the DOJ lawsuit, which is this thing I'm referring to with my idiot doctors doing poor documentation* and you combine that with Kim Parkinson not getting SPRs in New Jersey, you literally take six centers, which is more than a quarter of our business, you take it off the playing field. Are you with me? *And it's very expensive mistakes, serious mistakes.*

Id. at 186:19-25 (emphasis added).

230. McGuckin's admissions, in writing and in testimony given under oath, coupled with his self-reporting that his PAD procedures are on patients who do not meet the criteria for such invasive procedures, demonstrate that Defendants' conduct was knowing under the FCA.

F. Defendants' Excessive and Medically Unnecessary PAD Procedures Cost the United States Millions of Dollars.

231. Based on a statistically valid random sample of claims Defendants submitted (or caused to be submitted) to Medicare using four specific CPT Codes for PAD procedures (37227, 37229, 37252, and 37253) performed by McGuckin personally between 2016 and 2019, the United States paid at least $6.5 million for over 500 false claims that were not medically necessary and/or insufficiently documented as such.

232. There is evidence that Defendants submitted similarly false claims: (1) for procedures using other CPT codes for PAD procedures (including, by way of example, 37224, 37225, 37226, 37228, 37230, 37231, 37232, 37233, 37234, and

37235); (2) on behalf of other providers practicing at the defendant entities; and (3) beyond the relevant period, including through the present.

233. Accordingly, the United States estimates that its damages far exceed its estimate based on its original sample.

234. Just based on the four CPT codes used in the sample, Defendants are liable to the United States for treble damages in the amount of $19.5 million, and civil penalties of no less than $6,754,000, using the applicable minimum penalty rate.

VI. DEFENDANTS KNOWINGLY AND WILLFULLY PAID KICKBACKS IN THE FORM OF WAIVED MEDICARE COPAYMENTS AND MISREPRESENTED THE TRUE COST OF THEIR SERVICES.

235. Defendants inappropriately waived Medicare copayments, assuring that certain patients had no financial incentive to question the necessity of the excessive cardiovascular procedures to which Defendants subjected them.

236. Upon information and belief, Defendants failed to satisfy the conditions established by Medicare laws, regulations, and program instructions to support those copayment waivers.

237. Upon information and belief, Defendants told patients that they would not have to pay for Defendants' services, and that insurance payments, including Medicare payments, would be treated as payment in full.

238. Upon information and belief, where possible, Defendants collected copayments from secondary insurances including Medicaid and Medigap, but

regularly did not collect copayments from federal beneficiaries who lacked supplemental coverage.

239. During the relevant period, Defendants knowingly submitted or caused the submission of claims to Medicare that were false because: (a) they were tainted by the knowing and willful offer and/or provision of kickbacks in the form of unjustified copayment waivers; and (b) they misrepresented the actual cost of Defendants' services. Specific examples of these false claims are set forth below.

A. Defendants Understood and Disregarded Medicare Laws, Regulations, and Program Instructions Regarding Medicare Copayment Collection.

240. Defendants understood the rules governing Medicare copayments, and the circumstances under which the waiver of a Medicare copayment was permissible.

241. According to their policies, Defendants verified insurance overage two weeks before performing a procedure and notified patients of any copayment several days prior to the date of their procedure so that they could make arrangements to pay on the day of their surgery.

242. Additionally, Defendants' policies stated that copayment-related information was to be placed in the patient's electronic file.

243. Defendants' patient files included benefits statements for Medicare beneficiaries that showed that Medicare beneficiaries were generally responsible for 20 percent of the amount of the procedure.

244. Defendants also had a specific "Charity Policy."

245. Defendants' Charity Policy expressly acknowledges that patients' financial responsibility can only be discounted in limited circumstances in accordance with federal guidelines set forth by HHS.

246. More specifically, according to Defendants' Charity Policy, patients who are low income or indigent must complete an application for financial assistance, including federal tax returns, and submit it prior to the scheduled date of their procedure to allow for review by Defendants.

247. Pursuant to the Charity Policy, Defendants were supposed to send a letter of confirmation with the results of the review, with a copy in the patient's chart.

248. The Charity Policy includes sample applications and approval/denial notices.

B. Defendants Disregarded the Requirements and Waived Medicare Copayments.

249. Throughout the relevant period, Defendants' policies show that they knew the requirements for waiving Medicare copayments, including on account of financial hardship, and yet Defendants knowingly, deliberately, and/or recklessly disregarded those policies in violation of the AKS and FCA.

250. Below are examples of Defendants' patients whose copayments were completely written off as "Charity."

251. Neither of these patients had any documentation to support the Defendants' "Charity" write off of the copayment.

PATIENT RD

252. Patient RD was referred to PVI by Dr. Arnold.

253. PVIP submitted claims for services rendered to Patient RD by McGuckin on April 4 and 8, 2019 under CPT Codes 37225 (femoropopliteal atherectomy/angioplasty/stent), 37252 (initial use of IVUS), 37253 (subsequent use of IVUS), 75716 (diagnostic imaging), 75625 (x-ray), 99152 (sedation), 76937 (ultrasonic guidance procedures).

254. Medicare paid Defendants $12,437.83 for these procedures.

255. Patient RD paid nothing for these procedures.

256. The financial records for Patient RD show a "Charity Write Off" of $3,122.93.

257. However, despite Defendants' Charity Policy, upon information and belief, there is no documentation to support the Charity Write Off for Patient RD.

258. Additionally, financial records for Patient RD show a "Medicaid Adjustment" of $11,743.76.

259. RD was not a Medicaid beneficiary and Defendants never received any payments from Medicaid, only Medicare.

260. Indeed, Defendants submitted claims to Medicaid as secondary payer for these services but the claims were denied because RD was not a Medicaid beneficiary.

261. Defendants' failure to collect any of the thousands of dollars owed in copayments from Patient RD induced him, at least in part, to undergo various procedures, which were ultimately reimbursed only by Medicare.

262. The Medicare claims described above were false because they misrepresented the actual cost of Defendants' services and were tainted by the knowing and willful provision of a kickback in the form of an unjustified copayment waiver.

PATIENT MH

263. LVVI submitted claims for services rendered to Patient MH by McGuckin between July 12, 2019 and December 10, 2019, under the following CPT Codes: 37225 (femoropopliteal angioplasty with atherectomy), 37227 (femoropopliteal atherectomy/angioplasty/stent), 37229 (tibial atherectomy/ angioplasty), 37221 (iliac stent/angioplasty), 37252 and 37253 (for initial and subsequent uses of IVUS), 75710 and 75716 (x-rays), 75625 (aortogram), 76937 (vascular ultrasound guidance), 93923, 93925, 93926, 93978 (non-invasive artery imaging), 99213 (office visit), 99152 and 99153 (sedation).

264. Medicare paid Defendants $76,595.08 for these procedures.

265. Patient MH paid nothing for these procedures.

266. The financial records for Patient MH show a "Charity Write Off" of $19,476.60.

267. However, despite Defendants' Charity Policy, upon information and belief, there is no documentation to support the Charity Write Off for Patient MH.

268. Defendants' inappropriate failure to collect any of the thousands of dollars owed in copayments from Patient MH induced him, at least in part, to undergo various procedures, which were ultimately reimbursed only by Medicare.

269. The Medicare claims described above were false because they misrepresented the actual cost of Defendants' services and were tainted by the knowing and willful provision of a kickback in the form of an unjustified copayment waiver.

COUNT I

Violations of the False Claims Act: Presentation of False Claims 31 U.S.C. § 3729(a)(1)(A)

270. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

271. From at least January 1, 2016 to December 31, 2019, Defendants knowingly presented or caused to be presented materially false or fraudulent claims to the United States, including claims for reimbursement by the Medicare Program and the FEHBP that were false or fraudulent because they were for PAD procedures that were not medically necessary and/or were not properly documented, in violation of the FCA, 31 U.S.C. § 3729 (a)(1)(A).

272. Defendants caused the United States to pay at least $6.5 million for over 500 false claims related to the four CPT Codes sampled alone, and probably more.

273. As detailed above, the Medicare Program and the FEHBP would not have otherwise paid these false or fraudulent claims.

274. Defendants presented these claims or caused these claims to be presented, with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard of whether or not they were false.

275. Defendants are jointly and severally liable to the United States for damages in an amount to be determined at trial, but not less than $6.5 million in damages, trebled, as well as civil penalties of not less than $13,508 and not more than $27,018 for each false claim submitted to the Medicare Program and the FEHBP, or as further adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5.

COUNT II

Violations of the False Claims Act: Making or Using False Statements Material to a False Claim 31 U.S.C. § 3729(a)(1)(B)

276. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

277. From at least January 1, 2016 to December 31, 2019, Defendants knowingly made, used, or caused to be made or used, false records or statements that were material to false or fraudulent claims for payment or approval by the Medicare Program and the FEHBP for PAD procedures that were not medically necessary and/or not properly documented, in violation of the FCA, 31 U.S.C. § 3729 (a)(1)(B).

278. The false records or statements appeared on CMS Form 1500 and/or its electronic equivalent, the 837P Form—where Defendants falsely certified to the United States, *inter alia*, that the PAD procedures for which they sought payment were medically necessary—and on CMS Forms 855b and 855i–where Defendants falsely certified to the United States, *inter alia*, their compliance with all "Medicare laws, regulations and program instructions."

279. Defendants made these false representations for the purpose of causing to pay their false or fraudulent claims, which was the reasonable and foreseeable consequence of Defendants' statements and actions.

280. The false records or statements were material to Defendants' claims for payment of the false claims because the Medicare Program and the FEHBP would not have paid the claims absent the records or statements.

281. Defendants presented these claims or caused these claims to be presented, with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard of whether or not they were false.

282. Defendants are jointly and severally liable to the United States for damages in an amount to be determined at trial, but not less than $6.5 million in damages, trebled, as well as civil penalties of not less than $13,508 and not more than $27,018 for each false claim submitted to the Medicare Program and the FEHBP, or as further adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5.

COUNT III

Violations of the False Claims Act:
Presentation of False Claims (Kickbacks)
31 U.S.C. § 3729(a)(1)(A)

283. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

284. From at least January 1, 2016 to December 31, 2019, Defendants knowingly presented or caused to be presented false or fraudulent claims to the United States for payment or approval, in violation of the FCA, 31 U.S.C. § 3729(a)(1) (1986), amended by 31 U.S.C. § 3729(a)(1)(A) (2009).

285. Upon information and belief, the claims were false or fraudulent because they were tainted by kickbacks that Defendants knowingly and willfully provided to Medicare beneficiaries in the form of copayment waivers, at least one purpose of which was to induce the beneficiaries to obtain additional medical services from Defendants paid for by the Medicare Program, in violation of the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b), (g).

286. The claims also were false or fraudulent because they overstated the cost of the Defendants' services by the amount of the inappropriately waived beneficiary copayments and therefore resulted in inflated claims to the Medicare Program for payment of such services.

287. Because of Defendants' false or fraudulent claims, the United States suffered damages.

288. Defendants are jointly and severally liable to the United States for damages in an amount to be determined at trial, but not less than $89,032.91 in damages, trebled, as well as civil penalties of not less than $13,508 and not more than $27,018 for each false claim submitted to the Medicare Program, or as further adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5.

COUNT IV

Violations of the False Claims Act:
Making or Using False Statements Material to a False Claim (Kickbacks)
31 U.S.C. § 3729(a)(1)(B)

289. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

290. As a result of willfully offering unjustified copay waivers to induce Medicare beneficiaries to receive additional services from Defendants, Defendants caused to be made or used false records that were material to false or fraudulent claims to Medicare.

291. These false records and statements included false certifications on provider enrollment forms and false and misleading representation on CMS claims form that the claims to Medicare complied with the AKS when in fact those claims were tainted by AKS violations.

292. Accordingly, Defendants knowingly caused to be made or used false records or statements material to false or fraudulent claims to Medicare.

293. By reason of the false or fraudulent records or statements, the United States has been damaged in a substantial amount to be determined at trial, but not less than $89,032.91, in damages, trebled, as well as civil penalties of not less than $13,508 and not more than $27,018 for each false claim submitted to the Medicare Program, or as further adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5.

COUNT V

Payment by Mistake (False Claims)

294. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

295. The United States paid the claims described in this Complaint as a result of mistaken understandings of fact. Specifically, the United States paid those claims under the mistaken understanding that Defendants' PAD procedures were reasonable, medically necessary, and properly documented, such that the United States mistakenly believed Defendants were entitled to receive payment for such claims.

296. The mistaken understanding of the United States was material to its decision to pay Defendants for such claims.

297. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendants' certifications and representations that the claims were accurate, complete, and truthful, in accordance with the

Medicare Program and the FEHBP, paid Defendants certain sums of money to which Defendants were not entitled.

298. The United States has been damaged because of this mistaken payment, and Defendants are thus liable to account for and pay to the United States such amounts, which are to be determined at trial.

COUNT VI

Payment by Mistake (Kickbacks)

299. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

300. The United States paid the claims described in this Complaint as a result of mistaken understandings of fact. Specifically, the United States paid what it believed was 80 percent of those claims under the mistaken understanding that Defendants were collecting the remaining 20 percent beneficiary copayment.

301. The mistaken understanding of the United States was material to its decision to pay Defendants for such claims.

302. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendants' certifications and representations that the claims were accurate, complete, and truthful, in accordance with the Medicare Program, paid Defendants certain sums of money to which Defendants were not entitled.

303. The United States has been damaged because of this mistaken payment, and Defendants are thus liable to account for and pay to the United

States such amounts, but not less than $89,032.91 in damages, which are to be determined at trial.

COUNT VII

Unjust Enrichment

304. The United States incorporates by reference the foregoing paragraphs as though fully set forth herein.

305. From at least January 1, 2016 to December 31, 2019, the United States paid Defendants for medically unnecessary and/or improperly documented PAD procedures.

306. By directly or indirectly obtaining federal funds from the Medicare Program and the FEHBP to which they were not entitled, Defendants were unjustly enriched at the expense of the United States and are liable to account and pay to the United States such amounts, or the proceeds therefrom, which are to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor and against Defendants, jointly and severally, as follows:

I. On Counts I, II, III, and IV under the FCA, against all Defendants jointly and severally, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law.

II. On Counts V and VI for payment under mistake of fact, for an amount equal to the money paid by the United States to Defendants to which Defendants were not entitled, plus interest, costs, and expenses.

III. On Count VII for unjust enrichment, for an amount equal to the monies that the Defendants obtained from the United States without right and by which they have been unjustly enriched, plus interest, costs, and expenses.

IV. All such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial.

Respectfully submitted,

/s/ Jacqueline C. Romero
JACQUELINE C. ROMERO
United States Attorney

/s/ Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/ Charlene Keller Fullmer
CHARLENE KELLER FULLMER
Assistant United States Attorney
Deputy Chief, Civil Division

/s/ Lauren DeBruicker
LAUREN DeBRUICKER
MATTHEW E. K. HOWATT
Assistant United States Attorneys
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
(215) 861-8492/8335
Lauren.DeBruicker@usdoj.gov
Matthew.Howatt@usdoj.gov

Date: May 1, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May, 2023, I served a true and correct copy of the foregoing Complaint in Intervention via ECF on the following counsel of record:

Timothy Kolman, Esq.
Kolman Ely, P.C.
414 Hulmeville Ave.
Penndel, PA 19047

Relator's Counsel

/s/ Lauren DeBruicker
LAUREN DeBRUICKER
Assistant United States Attorney